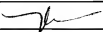


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PTO/SB/33 (07-05)

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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 1001.1674101	
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on <u>FEBRUARY 1, 2008</u> Signature 		First Named Inventor DAVID J. PARINS	
Typed or printed name <u>THU H. LE-TO</u>		Art Unit 3736	Examiner J. HOEKSTRA

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. ☒

This request is being filed with a notice of appeal. ☒

The review is requested for the reason(s) stated on the attached sheet(s). ☒
Note: No more than five (5) pages may be provided.

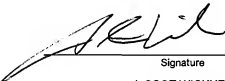
I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 41,376

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____


Signature
J. SCOT WICKHEM
Typed or printed name
612.677.9050
Telephone number
February 1, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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P A T E N T

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: DAVID J. PARINS

Confirmation No.: 8129

Serial No.: 10/656,630

Examiner: J. HOEKSTRA

Filing Date: SEPTEMBER 5, 2003

Group Art: 3736

Docket No.: 1001.1674101

Customer No.: 28075


Title: MEDICAL DEVICE COIL

PRE-APPEAL CONFERENCE BRIEF

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Thu H. Le-To

FEBRUARY 1, 2008

Date

Dear Sirs:

Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a prima facie rejection.

Claims 1-33 are rejected under 35 U.S.C. §103(a) as being unpatentable over Golds (US 6,312,458 B1) in view of Richardson et al. (US 2001/0009980). The Examiner acknowledges that Golds fails to teach a thermoplastic polymer tube circumferentially disposed about a portion of the coil length. The Examiner asserts that Richardson et al. teaches a medical device including a thermoplastic polymer tube 26, 46 circumferentially disposed about a portion of a helically wound coil length, and the tube affixed to the coil. The Examiner then asserts that it would have been obvious to substitute the thermoplastic tube of Richardson for the "sleeve" (securement member 20) of Golds because both Golds and Richardson teach intracorporal medical devices with thermoplastic elements affixed to a portion of a length of a helical coil, and the substitution would have been expected to achieve

the predictable results of configuring the torque transmission, pushability, and flexibility of an intracorporal medical device for navigating tortuous vasculature. Applicants respectfully disagree.

Golds teaches:

The design allows securement of a stent to a graft in such a manner to ensure optimal properties of flexibility and reduced profile. Specifically, the helical angularly oriented direction of the securement member, which is wrapped circumferentially around the tubular member creates an angle with respect to the longitudinal axis of the tubular member which is incongruous to the angle at which the windings of the stent are disposed with respect to the longitudinal axis of the prosthesis. This allows for structural integrity of the prosthesis with a minimal amount of material comprising the securement member.

Emphasis added; see column 4, lines 38-48, and FIGS. 4 and 5. Golds also teaches:

As shown in FIG. 4 of the drawings, securement member 20 is helically arranged at a second angle .beta. which is non-congruent to said first angle .theta.. This design construction allows the prosthesis to be thin-walled, compliant, and more flexible, because it provides structural integrity using less covering in the form of securement member 20. When securement member 20 is angled at a different angle (as compared to angle .theta. between the stent windings and axis) to longitudinal axis 22, it allows the securement of the stent to the graft using less material than previously used in prostheses of this type. More specifically, the angular arrangement of the securement member allows a thin securement member, which allows for a more flexible, and thinner composite prosthesis. Both angle .theta. and angle .beta. may equal any value from 0.degree. to 180.degree. with respect to longitudinal axis 22.

Golds thus appears to teach the securement member 20 as a thin tape-like structure, and teaches that such structure provides specific advantages, including a prosthesis that is “more flexible, because it provides structural integrity using less covering”.

Richardson appears to teach a guidewire with multiple polymer jackets over the distal and intermediate areas. In particular, Richardson teaches:

In embodiments where the guide wire has a shapeable coil over a core member, it may be desirable to configure the process so that gaps between the turns of the coil and between the coil and the core member are filled with polymeric material to minimize any air voids.

See paragraph 0012. Richardson also teaches:

In some embodiments, it may be preferable to configure the guide wire so that any spaces between the individual coils of the helical coil 22 or between the coil 22 and the core member 18 are substantially filled by polymeric jacket 28.

Emphasis added; see paragraph 0021. Richardson specifically teaches:

The polymeric materials should be processed so that they conform closely to the elongated core member and the shapeable distal tip. Preferably, tubes or sleeves of polymeric material are hot die necked onto the guide wire. As an alternative, tubes or sleeves of suitable polymeric material can be heat shrunk over an elongate core member to produce the desired result. In some embodiments, it may be desirable to minimize any air gaps between the helical coil itself or between the coil and the core member. This may be achieved by heating the die to assure the polymer flows into the coil.

Emphasis added; see paragraph 0026. Richardson thus appears to teach that it is desirable in embodiments having a coil wrapped around the distal end, to fill any spaces between the coil and the core with the polymer jacket. Applicants submit that a combination of Golds and Richardson would appear to result in a guidewire having a coil at the distal end, covered with a polymer layer to fill the gaps between the coil and core member.

The Examiner appears to be asserting that the tape-like securement member 20 of Golds is equivalent to the polymer jacket of Richardson. Applicants respectfully disagree. As seen in the quoted passages above, Golds specifically teach advantages of their tape-like securement as providing structural integrity using less covering material, while increasing flexibility. Richardson, however, appears to teach the importance of filling the gaps between a coil and the core member with polymer to achieve the desired distal tip characteristics without air voids. Applicants submit that one of ordinary skill in the art would not consider the tape-like securement of Golds and the polymer tube of Richardson as equivalents because they have different structures and are designed to provide different properties to the guidewire.

Further, one of ordinary skill in the art would have no reasonable expectation of success in substituting the polymer tube of Richardson for the tape-like securement member of Golds due to the differing structures and properties of the two members. Richardson specifically teaches that in embodiments having a coil disposed about a core member, the

polymer tube is preferably flowed into the coil to avoid air voids. See paragraphs 0012 and 0026. Golds, however, appears to teach advantages in having a tape-like securement member that is adhered non-continuously at selected areas or continuously adhered through its entire length. The different structures of the tape of Golds and the flowed polymer of Richardson cannot be seen to be equivalent, either in structure or function. Thus, there is no motivation for one of ordinary skill in the art to attempt to substitute the polymer tube of Richardson for the tape of Golds.

The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006):

“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”.

Emphasis added; see page 14 of the April 30, 2007 decision. The Court further stated:

a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

See page 14 of the April 30, 2007 decision. In view of the above-discussed structural and functional differences between the polymer tube of Richardson and the tape of Golds, Applicants submit that the Examiner's assertion of substituting the polymer tube of Richardson for the tape of Golds would have been obvious to achieve predictable results of configuring the torque transmission, pushability, and flexibility of an intracorporal medical device has no rational underpinning. In particular, Golds teaches the tape-like securement member allows securement of a stent to the graft using less material than previous embodiments, allowing for structural integrity and increased flexibility with a minimal amount of material. See column 3, lines 1-7; column 4, lines 38-48; column 6, lines 10-24. Applicants submit that there is no rational reason for one of ordinary skill in the art to conclude that substituting the polymer jacket flowed into a coil, as taught by Richardson, for the tape-like securement of Golds would achieve “predictable results of configuring the torque transmission, pushability, and flexibility” as asserted by the Examiner. It appears to Examiner has made a conclusion of obviousness merely by demonstrated that several

elements of the claims are independently known in the prior art, which is not a valid basis for obviousness.

Regarding claims 4, 7, 12, 15, 20, 23, 28, 31, and 33, the Examiner asserts that Applicant has not disclosed that a density of discrete affixation points per unit length has an advantage, is used for a particular purpose, or solve a stated problem, thus it appears to be an arbitrary design consideration which fails to distinguish over Golds in view of Richardson. Applicants respectfully disagree. The Examiner's attention is directed to the specification at, for example, page 8, line 20 through page 2, for a discussion of the enhanced torque transmission along the coil length and enhanced pushability while providing flexibility due in part to the number and size of discrete affixation points along the length of the coil. The features of the dependent claims are thus not merely design considerations but provide functional and structural differences that distinguish the claimed device from the prior art. Reconsideration and withdrawal of the rejection are respectfully requested.

It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is also respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

DAVID J. PARINS

By his attorney,

Date: February 1, 2008


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